Message

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Sent: 9/26/2018 12:35:31 PM
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Subject: EtO + PEER sues EPA for release of formaldehyde IRIS documents | InsideEPA.com

There is also a story about ETO today

ACC Asks EPA To Correct Ethylene Oxide Risk Level After Chloroprene Deal

September 25, 2018

The chemical industry is targeting for correction EPA's combined use of its Integrated Risk Information System (IRIS) assessment for ethylene oxide (EO), a sterilizer chemical, and air toxics modeling data, a request that could be bolstered by the agency's recent agreement to review similar industry concerns over EPA oversight of chloroprene.

The American Chemistry Council (ACC), the industry's major lobbying arm, Sept. 25 filed a request for correction (RfC) with EPA under the Information Quality Act (IQA) asking the agency to withdraw data on ethylene oxide in its recently issued National Air Toxics Assessment (NATA) that relied on its 2016 IRIS values for the chemical.

"The 2014 NATA does not meet the IQA's data quality requirements because the EO IRIS Assessment is not the best available science. Therefore, the 2014 NATA risk estimates for EO should be withdrawn and corrected to reflect scientifically-supportable risk values," ACC's petition says.

The group also urged EPA to refrain from using the IRIS assessment's cancer risk values to calculate EO risk in its risk and technology reviews (RTRs) to determine whether current air toxics rules are protective.

While the IQA requires EPA to respond, courts have found the law is not judicially reviewable so petitioners usually lack a means of enforcing any petition.

The NATA, based on the 2016 IRIS values and updated emissions inventory modeling, suggested persistent cancer risks from the chemical, which has long been suspected of causing breast and lymph cancers but is commonly used as an intermediate to make other chemical products like detergent, antifreeze and polyester, and to sterilize medical equipment and foods.

EPA has launched RTRs of some air toxics rules to determine whether they are adequately protective.

The NATA and underlying IRIS values have already prompted significant concerns in an area outside Chicago, where local residents and their congressional representative are urging EPA to demonstrate that EO emissions from a medical sterilization plant "are no longer a threat to public health or use its authority under Section 303 of the Clean Air Act to shut down the plant," Rep. Dan Lipinski (D-IL) wrote in a Sept. 24 letter to EPA Administrator Andrew Wheeler.

Lipinski notes in the letter that the plant's operating permit from the Illinois EPA was issued in 2015, before the IRIS assessment was completed, "and therefore does not take the updated risk assessment into account."

ACC's move appears to follow the playbook of the Denka Performance Elastomer company, which filed a similar RfC after EPA combined 2011 NATA modeling with the 2010 IRIS assessment of chloroprene to bring an enforcement action to address concerns about the carcinogenicity of chloroprene emissions from Denka's neoprene plant in Louisiana.

The modeled cancer risk for those living near Denka's LaPlace, LA, facility led to regulatory oversight from EPA and the Louisiana Department of Environmental Quality.

After EPA denied the RfC last January, Denka spent $30 million on pollution-reduction controls on its plant, though the company says the controls will still not enable it to meet the emissions standard that regulators have set for it based on what they view as the flawed IRIS assessment.

Over the past summer, EPA and Denka officials reached an agreement that has the potential for EPA to re-open the IRIS assessment. Under the deal, Denka is funding the development of a new model that could be used to update the IRIS assessment. EPA has agreed to review it and seek expert peer review of it if deemed acceptable by EPA modelers.

IRIS Assessment

EPA's agreement to reconsider its IRIS assessment for chloroprene is a potentially precedent-setting one, given that the agency's influential IRIS assessments, often used as the basis for regulatory decision-making, are often criticized as overly stringent by industry and other regulated entities, such as the Defense Department.

In the case of EO, however, ACC does not appear to propose creation of a new model, suggesting instead that the agency simply use an existing industry model, published six years before the IRIS assessment was finalized, to revise its 2016 analysis.

ACC did not respond to a request for comment by press time.

EPA's 2016 IRIS assessment set an inhalation unit risk estimate (IUR), or cancer potency estimate, of 5 x 10-3 per micrograms per cubic meter (ug/m3), which corresponds to a one-in-a-million increased cancer risk concentration of 0.1 parts per trillion (ppt).

The 2016 assessment's IUR is based on human epidemiology data of both incidence of lymphoid cancers and breast cancer. Part of its stringency is due to use of an Age Dependent Adjustment Factor, an extra measure of safety EPA uses when a chemical is considered to be of particular risk to children.

The 2016 IRIS assessment's IUR is significantly stricter than that EPA calculated for EO in a previous analysis of the chemical in 1985, of 1 x 10^-4 per ug/m^3.

But industry argued throughout its drafting the 2016 IRIS assessment, sets a cancer potency estimate that is overly strict, particularly for a naturally-occurring chemical with EO's benefits.

ACC reiterates those concerns in its RfC and urges EPA to refrain from using the IRIS values in the ongoing RTR, as well as any other regulatory action.

It cites as an example an air toxics rule EPA proposed earlier this month for "Surface Coating of Large Appliances; Printing, Coating, and Dying of Fabrics and Other Textiles; and Surface Coating of Metal Furniture Residual Risk and Technology Reviews," where the agency seeks "comment on whether it should ban the use of EO for one of the source categories."

The "risk estimates based on the EO IRIS value have significant regulatory implications for ACC member companies who produce commercial products of value to consumers using EO. Correcting these deficiencies will result in more accurate estimates of potential risk that will lead to improved regulatory outcomes, the dissemination of more accurate information to the public, and overall reduced misconception."

ACC argues that the IRIS assessment is inaccurate for several reasons, including its use of a model for cancer risk from environmental exposure levels called a "supralinear spline." ACC charges this model "predicts high risk at low exposures, lower risk at higher exposures, and estimates an unrealistically low concentration of 0.1 ppt."

EPA performed the calculations with the spline model using lymphoid and breast cancer data from an epidemiology study conducted by the National Institute for Occupational Safety and Health (NIOSH).

But ACC argues that the EO assessment's risk estimates are, "implausible" and "lack utility for regulatory purposes. The [1 in 1 million incidences of cancer-based risk specific concentration (RSC)] in the EO IRIS Assessment is 19,000 times lower than the air-concentration equivalent yielding normal, endogenous levels of EO in the human body. Likewise, the RSC is orders of magnitude lower than ambient levels of EO. Thus, if the EO IRIS Assessment is to be believed, normal human metabolism and/or breathing ambient air is sufficient to cause cancer. The EO IRIS Assessment does not provide a meaningful basis for assessing and managing risk for EO."

In its stead, ACC argues that the IRIS assessment "can be corrected" by adopting the approach taken by Exponent consultants in a 2010 publication using a different cancer risk modeling approach, the log-linear Cox model, and including another epidemiology study with the NIOSH study. -- *Maria Hegstad* (mhegstad@iwpnews.com)

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Subject: PEER sues EPA for release of formaldehyde IRIS documents | InsideEPA.com

https://insideepa.com/daily-feed/peer-sues-epa-release-formaldehyde-iris-documents

PEER sues EPA for release of formaldehyde IRIS documents

A government watchdog group is suing EPA over its failure to turn over documents that could explain the agency's delay in releasing a long-promised draft assessment of the human health risks of exposure to formaldehyde, which former Administrator Scott Pruitt said was completed a year ago.

Public Employees for Environmental Responsibility (PEER), a group that represents EPA and other personnel, sued the agency in federal court in Washington, DC, charging that it is violating the Freedom of Information Act (FOIA) because it has not responded to a request filed last July.

PEER says that EPA failed to meet the statutory deadline to respond to the request, and "has yet to produce any of this material."

PEER's FOIA request sought any drafts of EPA's Integrated Risk Information System (IRIS) formaldehyde assessment prepared since 2015; any communications between former Administrator Scott Pruitt or acting Administrator Andrew Wheeler regarding the assessment; any records related to a meeting last January between officials of the American Chemistry Council's Formaldehyde Panel and EPA; any communications regarding the assessment between ACC's panel leader regarding the assessment and any "recommendations or requests to EPA from non-EPA employees or contractors about the release or delay of" the IRIS assessment since 2017.

EPA has so far failed to release its draft formaldehyde assessment despite a pledge in EPA's report to Congress last January on the IRIS program that the draft would be released by the end of the fiscal year on Sept. 30.

Last May, Democratic Sens. Tom Carper (DE), Ed Markey (MA) and Sheldon Whitehouse (RI) wrote Pruitt to speed the release of the draft assessment. In the letter, they said EPA concluded in the 2017 draft as it did in a 2010 draft assessment, that formaldehyde exposure can lead to leukemia, a finding that industry groups strongly oppose because it could drive significant new liabilities.

Their letter alleged that the draft formaldehyde assessment was completed "during the fall of 2017," but has yet to proceed through the regular intra-agency review process normally undertaken before the document is released for inter-agency review, public comment, and peer review. They argued that EPA has yet to release the draft document because "multiple political appointees within EPA have expressed reluctance to move the assessment through the agency review process, have repeatedly set up briefings on the assessment only to later cancel them, and/or have insisted that IRIS first set up briefings for industry stakeholders before completing agency review."

The senators named Pruitt's chief of staff Ryan Jackson, air office chief Bill Wehrum and toxics office appointee Nancy Beck as among those delaying the formaldehyde assessment's public release.

Asked about the draft assessment's status at an Aug. 1 hearing of the Senate environment committee, acting EPA Administrator Andrew Wheeler said he is reviewing the "accuracy" of the document prior to its release, issuing his first public assurance that the agency will ultimately make public the controversial review.

"I'm sure that we will release it, but I need to make sure that the science in the report is still accurate, and what I've asked, not just for that report but for everything that we're doing on the IRIS program, [is] to make sure that we know the purpose of the assessment," Wheeler said.

"So far, EPA has shared this important, tax-supported science with industry but not the public," PEER's staff counsel Kevin Bell says in a Sept. 25 statement, adding that "EPA has no legal basis for withholding reports that it has already disclosed to outside parties.

"EPA's current leadership often talks the talk about scientific transparency, but we have yet to see them walking," Bell said.

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